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Design for Patient Safety: A Systems-based Risk Identification Framework

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Name & Affiliation

Abstract

Current risk identification practices applied to patient safety in healthcare are insufficient. The situation can be improved, however, by studying systems approaches broadly and successfully utilised in other safety-critical industries, such as aviation and chemical industries.

To illustrate this, this paper first investigates current risk identification practices in the healthcare field, and then examines the potential of systems approaches. A systems-based approach, called the Risk Identification Framework (RID Framework), is then developed to enhance improvement in risk identification. Demonstrating the strengths of using multiple inputs and methods, the RID Framework helps to facilitate the proactive identification of new risks.

In this study, the potential value of the RID Framework is discussed by examining its application and evaluation, as conducted in a real-world healthcare setting. Both the application and evaluation of the RID Framework indicate positive results, as well as the need for further research.

Practitioner Summary: The findings in this study provide insights into how to make a better amalgamation of risk identification inputs to the safer design and more proactive risk management of healthcare delivery systems, which have been an increasing research interest among human factor professionals and ergonomists.

Keywords: healthcare ergonomics; patient safety; risk identification; systems approach

1. Risk Identification in Patient Safety

In healthcare, a range of studies have been conducted to accelerate improvement in patient safety and quality of care, since the pioneer report '*To Err is Human: Building a Safer Health System*' published by the US Institute of Medicine (IOM, 2000). While earlier studies indicated the frequency of medical errors remains high worldwide (Classen et al., 2011; James, 2013; Kurutkan et al., 2015; Unbeck et al., 2013), some also suggested that further research is imperative to transform healthcare to make health systems safer for patients (Bates et al., 2001; Leape and Berwick, 2005; Wachter, 2004).

To accelerate improvement on patient safety, there is a growing awareness in Human Factors and Ergonomics (HFE) (Gurses et al., 2012). Various frameworks have been developed and

adopted with the support of HFE to improve healthcare in different ways (Carayon et al., 2014; Hettinger et al., 2015; Hignett et al., 2013; Jun et al., 2017). As one of the fundamental characteristics of the HFE, systems approaches have been proposed to result in important benefits to healthcare, in terms of identifying patient safety risks through comprehensive system coverage. However, systems approaches are still underused in healthcare in contrast to other safety-critical industries, such as aviation (Simsekler et al., 2015b).

As an important aspect of most systems approaches, it was found that proactive risk identification via prospective hazard analysis (PHA) methods are also underused in patient safety context (Ward et al., 2010). While other industries adopted such proactive systems-based risk identification approaches to provide more efficient and safer systems, healthcare is still relying mostly on reactive approaches, such as incident reporting and investigation (Card et al., 2014; Waterson and Catchpole, 2016). While little measurable evidence and improvements have been so far shown through such reactive approaches (Hudson et al., 2012), some further practical limitations, such as hindsight bias and underreporting, have been also experienced in healthcare (Kessels-Habraken et al., 2009; Sari et al., 2007).

Earlier studies investigated the adoption and applicability of systems-based proactive risk identification and assessment approaches, such as PHA methods, for the redesign of healthcare systems (Ward et al., 2010). It was found that there is only a very slow and sporadic adoption of PHA methods in healthcare (Lyons, 2009). Here, Failure Mode Effect Analysis (FMEA) can be mentioned as the only exception as it has gained greater acceptance in healthcare as the most widely used PHA method (Chiozza and Ponzetti, 2009; Ward et al., 2010). For instance, in the US, Joint Commission for Accreditation of Healthcare Organizations (JCAHO) requires accredited organizations to use FMEA as part of their organisational patient safety policies (Chiozza and Ponzetti, 2009). While FMEA has supported organisations to be more proactive, many limitations were also noted, mainly due to time and cost constraints (Linkin et al., 2005; van Tilburg et al., 2006). To overcome such constraints, recent studies recommended to adopt less time intensive methods, such as Structured What-If Technique (SWIFT), to help achieve comprehensive risk identification by spending less time (Potts et al., 2014). However, there is still no clear evidence regarding the effectiveness of such proactive methods in identifying patient safety risks.

In addition to such issues, a number of concerns were also raised about the validity and reliability of PHA methods in healthcare applications (Franklin et al., 2012; Shebl et al.,

2009; N. A. Shebl et al., 2012). For instance, earlier research showed that validation of PHA methods is methodologically challenging, despite a few investigations proving their reliability (Potts et al., 2014). Beyond this, only a few studies have highlighted the use of multiple reactive and proactive methods to successfully provide a comprehensive view of risk in a given healthcare system (Kessels-Habraken et al., 2009; Potts et al., 2014). Potts and colleagues (2014) also pointed out that PHA methods should not be used in isolation in providing a comprehensive description. However, there is no evidence in the healthcare literature of how well such an amalgamation, using multiple inputs from both reactive and proactive risk identification approaches, can be demonstrated. These issues taken together show that there is still a need to implement an improvement in risk identification, which will contribute to patient safety improvement.

In summary, it has been noted that proactive systems-based risk identification approaches are underused in patient safety context. Recent research also highlighted the need in healthcare field to adopt a new approach to identify and mitigate patient safety risks by learning from the experiences of other safety-critical industries (Hudson et al., 2012). The potential exists, therefore, for improving the risk identification process by identifying the areas needing improvement within current risk identification practices, and by adopting HFE characteristics, such as proactive systems approaches. In the proposed study, all these needs and requirements are aimed to be captured and then be merged into a new Risk Identification Framework (named as *RID Framework*), which can potentially demonstrate the strengths of different reactive and proactive inputs, while evolving a comprehensive risk view within a systems approach. The RID Framework would therefore provide fundamental guidance on the effective use of risk identification within the scope of risk management.

2. Capturing Requirements for the Proposed Risk Identification Framework

At the outset of the design process in the current study, data and information were methodically collected to help determine the generic and specific requirements to include in the proposed RID Framework. In developing a comprehensive list of requirements, real-life examples from healthcare and other safety-critical industries were reviewed to capture the generic requirements.

To address requirements of the proposed RID Framework, it is imperative to obtain a better understanding of the current risk identification practice. Therefore, along with the literature review, research methods — including (1) *content analysis of NHS documents*, (2) *interview-based questionnaires*, and (3) *case studies* — were employed to understand current risk identification theory and practices in the healthcare field. First, in order to determine what support is currently provided for risk identification in healthcare, the current research included a content analysis of risk management policies and procedures from the NHS Trusts in the East of England region. While these documents were helpful in understanding and current theory in risk identification as applied to patient safety, it was also useful to become familiar with the diverse terminology used in healthcare procedural documents.

Further, the documents showed that incident reporting is the main method for risk identification in the chosen region, while providing insufficient support for the use of prospective risk identification methods, except safety walkabouts (see Simsekler et al., 2015b for more information). While content analysis provided significant insight into prescribed risk identification practice, we secondly conducted interview-based questionnaires to gain greater knowledge of current risk identification practices. The main focus of this stage was narrowing down the knowledge and experience healthcare professionals have regarding the practice of risk identification (see Simsekler, 2015 for more information). Similar to the findings in content analysis, we found limited knowledge on PHA methods, or any proactive systems approach, but emphasis on the use of incident investigation and safety walkabout in risk identification practice. Third, case studies were carried out to gain a greater understanding of the practical application of risk identification methods and their contribution to the overall risk identification practice (see Simsekler, 2015 and Simsekler et al., 2015a for more information).

Each research method provided valuable insight into current risk identification practices. As a result, we captured a range of requirements addressing the gaps and shortfalls in the current practice of risk identification. In particular, the findings showed a lack of systems approaches and safety culture to promote proactive risk identification. While the results showed no evidence of the use of PHA methods or systems approaches in the identification of risks, we also found that description and understanding of risk varies considerably among healthcare workers. As mentioned earlier, the content analysis and questionnaires showed that risk identification is mainly conducted through incident investigation and safety walkabouts, which are reactive and proactive, respectively. It was also found that risk registers also play

an important role in putting all risk information into a single picture; however, it appears that poor amalgamation of risk information from multiple methods is an impediment to the overall success of the risk identification process. These are the factors most in need of improvement in the current practice of risk identification.

In current risk identification practices, methods used for improving patient safety can be described with reference to their reactive or proactive natures. With respect to the current state of risk identification in healthcare, a link between reactive and proactive methods can be forged by constructing a bridge between incident investigation tools and safety walkabouts, as these two are most common methods currently used in healthcare (Simsekler et al., 2015b; Ward et al., 2010). Further, systems approaches, such as PHA methods, should be able to dovetail with the current methods in order to take advantage of their power thanks to their main inputs, such as brainstorming and use of system mapping approaches (SMAs, also known as process maps, process models). One of the suggestions of this study is that this can be accomplished with the implementation of a framework that provides a common, valid structure to bridge the several methods that can contribute to improving current risk identification practices.

While the analysis of current risk identification practice provided significant insight into the use of current inputs, such as incident investigation and safety walkabouts, we also analysed the usability of SMAs, the common inputs used in PHA methods as part of the HFE approaches (Wooldridge et al., 2017), along with brainstorming. We therefore investigated the potential contribution of such a framework, linked to currently employed methods, and propose a relationship involving current methods and inputs from PHA methods. In order to examine the contribution of different SMAs and brainstorming in the risk identification process, we carried out workshops on SMAs and FMEA in a formal risk identification exercise.

We evaluated a set of SMAs to assess their potential contribution to the identification of risks in a newly established mental health service. The key stakeholders of the chosen service, including clinicians, managers, and administrative staff, were individually asked to evaluate the following SMAs (based on the selection criteria in the PHA Toolkit (Clarkson et al., 2010)) according to their usefulness in identifying patient safety risks: *organisational, information, task, flow, communication, and system diagrams*. They were evaluated with the help of the risk categorisation framework, which classifies the risk sources as follows:

patient-sourced risks, staff-sourced risks, equipment-related risks, communication risks, task-related risks, organisational risks and environmental risks (Simsekler et al., 2015a).

Throughout the evaluation of the SMAs with healthcare staff, we noted that risk sources interacted in the system, and may have influenced the outcome of the delivery of care. It is therefore important to identify the description of the systems, their elements and interactions in a dynamic and complex healthcare context. The evaluation showed that SMAs are useful in risk identification. For instance, results showed that the *system diagram* is the most useful diagram for risk identification since it comprehensively represented how data and information are transferred through system activities. More importantly, the evaluation resulted that each type of SMA has a unique strength or limitation in identifying particular risk sources. For instance, the *flow diagram* was found as the most helpful diagram type in identifying *communication risks*, followed by the *communication diagram*. Throughout the evaluation workshops, we also found that amalgamation of the use of multiple SMAs can be helpful in identifying a comprehensive list of risks, though it may not be feasible to use all diagrams due to limited resources, such as limited time, resources, and experience of system users with SMAs (see Simsekler et al., 2018 for more information).

After running the evaluation workshops for SMAs, we then also conducted FMEA exercise to determine its contribution to the risk identification process, through the use of *system diagram*, since it was found as the most useful diagram for risk identification during the evaluation of the SMAs. Regarding the results of the FMEA exercise, we found that FMEA has merit in risk identification, but also had limitations in the selected healthcare context. Though FMEA provided a useful opportunity for risk identification along with the system diagram, we suggested that FMEA should not be used as a stand-alone tool in identifying patient safety risks. For instance, FMEA was limited in the identification of external and environmental risks, as the failure modes were only identified according to the process steps shown in the *system diagram* provided, and no identification of external risks was allowed. As with the previous results, we recommended that the outputs from FMEA should not be used in isolation (Ashley and Armitage, 2010; Franklin et al., 2012; N. Shebl et al., 2012; Shebl et al., 2009), but should be treated valuable to support the overall risk identification practice. Particularly, the primary inputs of this technique, brainstorming and the use of SMAs, can certainly contribute to the improvement of current risk identification practices.

We, so far, investigated gaps and shortfalls in current risk identification practices, and

provided insights into the potential contribution of the inputs, such as SMAs and brainstorming, used in most systems approaches. As a result of all findings, we developed a framework to merge all these requirements and learning points, as detailed in the following sections.

In order to organise these requirements, typical risk identification process characteristics, such as inputs, process [method(s)], and outputs, are used. Hence, all identified generic and specific needs were organised and adapted with regard to their specific characteristics to determine where they should be embedded into the proposed risk identification framework. Eighteen requirements were thus identified and categorised, as shown in Table 1.

--- Insert Table 1 about here ---

3. The Structure of the Risk Identification Framework

The requirements captured throughout the research are listed in Table 1. The proposed framework, which considers these requirements, is underpinned by a proactive systems-based approach to risk identification, and supports its users in understanding the overall system within a socio-technical perspective. The rationale behind the framework is an integrated approach to proactive risk identification, employing multiple inputs through brainstorming and safety walkabouts. The framework bridges the gap between reactive and proactive inputs, helping risk identification in healthcare become more proactive. The risk identification process, using this framework, could potentially show the strengths of using multiple approaches to enhance patient safety improvement.

The current research concluded that three stages should be defined in the structure of the framework, as depicted in Figure 1. These are (1) *system familiarisation*, (2) *identification of risks*, and (3) *presentation of risks*.

--- Insert Figure 1 about here ---

As shown in Figure 1, the risk identification framework includes a range of inputs, processes, and outputs in its structure. We aim to address each requirement through these three fundamental parts in the structure, as shown in the first three columns in Table 1. These are also detailed to provide fundamental guidance¹ to healthcare users.

3.1. Stage I: System Familiarisation

This stage considers a range of inputs to help increase understanding of the system, and awareness of potential patient safety risks that can occur in complex and changeable healthcare systems. The following steps are included in this stage.

Step-I System Description: It is important to have a clear system description, to increase understanding of how such systems behave, interact with their environment, and pose risks to patients. In this step, descriptions of the system, including its inputs, outputs, and boundary, are essential aspects.

The system description can be strengthened with two approaches, depending on available resources. These are (1) *brief textual and graphical system descriptions*, and (2) *system mapping approaches*. While such textual and graphical system descriptions are expected in all applications of the framework, the use of SMAs is suggested, depending on resource availability. Some flexibility is allowed in the RID Framework depending on the resource availability, and use of SMAs is one of the flexibility given.

- Brief Textual and Graphical System Description: Visual patient-centred maps can be used, or produced by participants, in this step. The objective of the system and its boundary are described, taking into account different system elements that directly or indirectly interact with the patients, subsystems, interfaces, and functions, while keeping patients at the centre of the system. Depending on availability, physical layouts and relevant documents can also be used to identify possible risk points in the selected healthcare environment.

- System Mapping Approaches: During risk identification, system descriptions can be supported through the use of SMAs. In addition to aiding the description of the system, such

¹ Full guidance on RID Framework can be found in the Ph.D. dissertation submitted to the University of Cambridge, titled as “Design for Patient Safety: A Systems-based Risk Identification Framework” (Simsekler, 2015).

approaches also strongly support identification of possible risk points in the context of patient safety. The framework considers six different SMAs, based on the PHA Toolkit (Clarkson et al., 2010). It may not always be feasible to use all diagram types in the risk identification process, due to time and cost constraints. Therefore, a number of criteria are suggested in the RID Framework for selecting the most appropriate SMA, depending on the nature of the healthcare system, as shown in Table 2. As detailed in our earlier study (Simsekler et al., 2018), the diagrams are marked with two different sizes of tick marks (bigger mark means more useful) indicating their usefulness in identifying particular types of risk sources.

--- Insert Table 2 about here ---

Step-II Risk Sources: Given dynamic and complex healthcare systems, different risk sources can trigger hazardous situations, potentially harming patients. It is therefore essential to consider as many risk sources as possible within a classification to help participants familiarise themselves with the given system and potential risk sources.

There are a number of classifications that can be used to categorise patient safety risk sources (Carayon et al., 2006; Rogers, 2002; Runciman et al., 2006). There are also extensive research on particular type of a risk source, such as environmental risks, indicating their impact on patient safety and quality of care in particular healthcare settings (Hignett and Lu, 2010; Joseph et al., 2017; Maben et al., 2016; Pati et al., 2016; Taylor and Hignett, 2016). While all studies may provide suitable vehicle for capturing potential risk sources, we particularly considered the National Patient Safety Agency (NPSA) Root Cause Analysis (RCA) contributing factors classification framework to use reactive inputs proactively to help transition between reactive and proactive approaches. While earlier research suggested the usability of the NPSA framework in risk identification (Card et al., 2012), our earlier evaluation via interview-based questionnaires also showed that most healthcare staff are familiar with this framework (Simsekler, 2015).

The NPSA framework lists the following factors: *patient factors, staff factors, organisational risks, communication factors, equipment factors, work environment factors, task factors,*

training and education factors, and team factors. However, as detailed in our earlier study (Simsekler et al., 2015a), it was sometimes difficult to differentiate the education and training factors, and the team factors, from organisational and staff-related risks. To obtain a more accurate classification, the final decision was made to use these factors as sub-classifications, subordinate to organizational risks and staff-sourced risks, depending on the situation. The following classification was therefore developed, subsuming most of the common classifications, such as The Systems Engineering Initiative for Patient Safety (SEIPS) model and the NPSA classification: (i) *patient-sourced risks*, (ii) *staff-sourced risks*, (iii) *equipment-related risks*, (iv) *communication risks*, (v) *task-related risks*, (vi) *organisational risks* and (vii) *environmental risks*.

As can be seen, the classification of risk sources is also correlated with the SMAs selected in this research. It is easy to describe the characteristic of interest using this categorisation, and select the most appropriate type of SMA during risk identification.

Step-III Nature of Hazards:

In dynamic and changeable healthcare systems, any deviation in the system might trigger hazards, potentially causing harm (Carayon et al., 2006). As the nature of the system elements is, in general, different, they can introduce different forms of hazards into the system being studied. It is therefore important to consider the different natures of hazards, because they can potentially influence the outcome of care delivered in changeable healthcare systems.

In order to distinguish the different natures of hazards, the following classification, produced by the Workplace Health and Safety Queensland (WHSQ) (2007) is used to stimulate the imagination of new risks in different natures:

- **The obvious hazard** is apparent to the senses
- **The concealed hazard** is not apparent to the senses
 - **The developing hazard** cannot be recognized immediately, and develops over time
 - **The transient hazard** is an intermittent or temporary hazard

This categorisation allows the identification of hazards present in the workplace. It can be applied to healthcare contexts, where the system is complex and therefore involves a variety

of different hazards. The use of this kind of categorisation can enhance the understanding of the system and its components' behaviour in the risk identification process.

Step-IV Time: Using this input, the users are expected to consider past, present, and possible future, to cover a range of risks. The following questions are considered in this stage:

- **Past:** *What has gone wrong in the past?*
- **Present:** *What could go wrong currently?*
- **Future:** *What could go wrong due to change?*

To consider the '*past*', it is important to review some examples of incidents that have previously occurred in the selected healthcare setting. A greater awareness of past errors increases users' knowledge about the chosen setting and the imagination of related risks. Depending on available time, different types of incidents can be considered in this step. In addition to incident reports, reactive results from claims and patient complaints can also be used to strengthen the bridge between reactive and proactive approaches.

Along with the past, '*present*' and '*future*' should be considered, to be more prognostic in risk identification. The categorisation of risk sources is suggested, to aid consideration of future areas of change, as prompts for imagining future risks. Hence, possible changes in technology, functions, and procedures are simply but explicitly considered, to capture additional risks that may not be identified by current risk identification methods used in healthcare.

Participants are therefore asked to identify both present and possible future risks (*due to change*), with the help of the categorisation of risk sources. For example, they are asked, "*What can go wrong in the system due to communication risks?*" The RID Framework is therefore expected to systematically consider the accumulation of interactions within and among the identified risk sources, thereby identifying new risks in given systems.

3.2. Stage II: Identification of Risks

At this stage, the aim is to gather multiple risk identification approaches, to provide an exhaustive list of risks. It should be noted that the framework aims to provide a systems approach, together with previous knowledge and experience gained through reactive approaches. Due to the different natures of the selected approaches, the potential exists to

identify different sets of risks, which helps to provide as much relevant risk information as possible for selected systems.

In the proposed RID Framework, the results of incident reporting (*past time* consideration as detailed in the previous section) are used as input to raise awareness of past errors, whereas brainstorming is promoted as the risk identification approach, together with safety walkabouts. In the proposed framework, the brainstorming approach (the main input in most PHA methods, along with SMAs) is incorporated into the centre of the framework, between the two most common practices, incident investigation and safety walkabouts. The aim is to build a bridge between reactive and proactive tools, and potentially provide better adoption of PHA inputs (*e.g.*, brainstorming and SMAs) to the current risk identification practice.

Combining multiple methods may seem redundant, and contradictory to the idea of the RID Framework, which is proposed as a less resource-intensive approach. To respond this, different methods were brought together with a number of selection criteria. In the framework, brainstorming is identified as the central approach, while safety walkabouts are an adjustable approach. This means that safety walkabouts can be omitted in some cases, depending on the nature of the specific healthcare systems. Another consideration in this stage is making the use of the framework easy and suitable for execution by individuals or teams. Inputs in brainstorming and safety walkabouts should be functional in both individual and team-based uses.

It can be said that using the proposed inputs may stimulate the imagination of new risks in a given system. Taking a systems approach, along with the categorisation of risk sources, the framework does not focus solely on safety risks that have occurred in the past, or on present risks, but aims to capture potential future risks as well. Therefore, possible changes in technology, medical and communication equipment, functions, and procedures within the seven categories are taken into consideration to identify and prepare for the emergent risks of the future, in complex healthcare systems. As an integrated approach, it is expected that the RID Framework will identify a richer set of risks than any single method would on its own. There is another suggestion here that while no one method would identify *all* risks in a given system, the proposed RID Framework gathers methods in a structured way, to help identify a broader list of risks in one picture.

Learning from the PHA methods and experience gained from the FMEA exercise provided

valuable insights for constructing a structure for brainstorming in the proposed RID Framework. As observed in the FMEA exercise, a systematic approach to identifying risks was established from a functional failure point of view (Simsekler, 2015). However, some potential risks were left unidentified. The system diagram was methodically followed in FMEA, and some environmental and external risks were therefore left unidentified, as they were not explicitly shown in the diagram. This is why, during brainstorming, the RID Framework considers the use of SMAs (if relevant) to identify hot spots, along with the classification of risk sources. It is therefore expected that risks outside the range of the functional approaches, such as FMEA, will be identified. Despite some inevitable overlap with other approaches, the use of the RID Framework should identify a more complete set of risks (at least in terms of quantity), as future risks are also considered in a structured way.

As pointed out in the literature, quantity breeds quality in risk identification (Smith et al., 2008). Therefore, the aim should be to identify as many risks relevant to given systems as possible. Another recommendation drawn from the literature is that criticism and analysis should be forbidden during brainstorming; preventing criticism provides the open atmosphere vital to productive brainstorming.

During safety walkabouts, healthcare workers are expected to use all the knowledge gained in the system familiarisation and brainstorming stages to identify a range of patient safety risks. During such walkabouts, the NPSA contributing factors classification framework can be used as a checklist.

3.3. Stage III: Presentation of the Risks

At this stage, the goal is to record the identified risks in a clear manner. Current methods in healthcare, such as incident reporting and safety walkabouts, had different approaches to recording these risks. As a result, it was difficult to list all risk information in one place, as they had different structures and contents. It is therefore important to properly define risks, to enable collaborative use with other tools and methods in case of integration.

As mentioned earlier, risk identification involves the identification of *risk sources*, *events*, *their causes*, and *their potential consequences*, according to the International Organization for Standardization (ISO 31000, 2008). Ericson (2005) similarly defined risk with three components: *hazardous elements*, *initiating mechanisms*, and *targets/threats*. In parallel to

these definitions of risk, most common PHA tools, such as FMEA and SWIFT, are used to identify similar components of hazards, causes, and possible effects. Taking such approaches into consideration, the following components are identified in the RID framework, to create a standard, structured description of risk:

- Hazard: *what can go wrong?*
- Potential cause: *why/how could it go wrong?*
- Potential effect: *who/what is at risk?*

In addition to the definition of risk itself, Ericson (2005) emphasised that the presentation of risk should be clear, concise, and descriptive, as this helps a worker other than the original analyst to completely understand the risk. Moreover, clear risk presentation is vital in risk assessment, since it might be time-consuming and redundant to spend a great deal of time mitigating a low risk mistakenly thought to be a high risk.

In addition to defining risk components, users are asked to identify the types of risk sources, to help understand that multiple risk sources can trigger hazardous situations.

The overall conceptual structure of the RID Framework is depicted in Figure 2. Two components are shown in dotted outlines in this figure; these are adjustable inputs, dependent on the availability of resources.

The presentation of the RID Framework with an example of a risk log sheet is presented in Table 3 as guidance.

--- Insert Figure 2 about here ---

--- Insert Table 3 about here ---

4. Evaluation of the RID Framework

4.1. Healthcare Setting

The study was conducted at Gastroenterology Unit at the Cambridge University Hospitals Foundation Trust (CUHFT) to evaluate the RID Framework. The Hospital has approximately 1,000 beds in total, employs over 7,000 staff, and offers the full range of local and tertiary services other than cardiothoracic surgery. As the chosen ward setting, the Gastroenterology Unit on Ward N2 is the designated ward for the care of gastroenterology patients. The beds in this ward are also available for patients who have acute *Clostridium difficile* infections. The ward has many tube-fed and line-fed patients. The ward managers therefore receive much input from nutrition nurse specialists, and work to ensure that the staff is trained in total parenteral nutrition (TPN) to help minimise the risk of infection. The ward has a number of different patients with special conditions, such as intestinal failure patients, and the ward managers want to help improve patient care.

4.2. Study Participants

In order to help produce representative samples by eliminating *voluntary bias* or *non-response bias*, the Patient Safety and Risk Unit at the Hospital was asked to select possible participants randomly. Seven participants were recruited in this case study to evaluate the RID Framework. Their job titles, experience in the NHS, and identifier codes are listed in Table 4.

--- Insert Table 4 about here ---

Because the participants in the study numbered only seven, outcomes may have been biased by each participant's personal experiences, and by their available time and motivation. Significant efforts were therefore made to minimise bias during the evaluation stage, as the outcome of this study constitutes a considerable portion of the study.

In the evaluation stage, there can be a tendency for respondents to indicate 'yes' or agree with questions, regardless of the questions' content; this is known as *acquiescence bias* (Breakwell et al., 2000). In order to preclude such bias, the purpose and the process of the study were made clear in advance. Confidentiality regarding responses was clearly stressed, and participants were encouraged to be open about the usability and utility of the RID

Framework. In order to identify issues that might cause participants to select the answer that favours positive results, the draft questionnaire was given to two clinicians as a formal pre-test, prior to its deployment to the actual participants. Such efforts were expected to be helpful in generalising the results from limited samples.

4.3. Data Collection

Two sets of data were collected in this study; the first included initial data about the chosen healthcare setting and were all collected prior to applying the RID Framework. This data collection was carried out with the help of the patient safety manager, based in the Patient Safety and Risk Unit, and the ward manager. As key participants in this study, these managers provided broad information about the ward, and all the inputs needed for the evaluation of the case study (*e.g.*, ward layout, possible participants' contact addresses, incident reports and risk registers from the chosen ward, etc.).

The second set of data was gathered to assess the usefulness of the RID Framework, using a questionnaire. Two concepts — usability and usefulness — are used to evaluate this framework. At the end of the case study sessions, therefore, participants were asked to provide their feedback on the usability and usefulness of the RID Framework. Based on Nielsen's description (Nielsen, 1993), Ward et al. stressed that the following factors should be considered when assessing usability and usefulness: *learnability*, *efficiency*, *memorability*, *errors*, and *satisfaction* (Ward et al., 2010). These were considered when selecting the content of the questionnaire. Having a questionnaire context similar to that of the work done previously, to evaluate the PHA Toolkit (Ward et al., 2010) was a particularly helpful resource in the development of the evaluation form. The content of that questionnaire helped to finalise the evaluation questionnaire used in the current research, which was presented to the participants to validate the usability and usefulness of the framework.

The complexity of the questionnaire was kept to a minimum, and its presentation in the workshop was carefully prepared. The questionnaire largely relied on closed questions, where participants were limited to choosing one option from a number of fixed alternatives. The workshop and questionnaire were also conducted as a pilot study, with a clinician who suggested alternative questions prior to the real-world case study application.

Evaluations were carried out using self-completed questionnaires, which, in contrast to

interview-based questionnaires, were considered for two reasons. It was thought, first, that some participants might prefer to complete the questionnaire when they had more time, and second, that brainstorming or safety walkabout sessions might take more time than expected, due to unforeseen factors. In such circumstances, the participants would be asked to fill out the self-completed questionnaire at a convenient later time.

4.4. Procedure

Before conducting the case study, the authors created clear procedure, describing how to conduct the study. Thanks to the flexible nature of the RID Framework, it was possible to make two adjustments in this study. The first adjustment was not using the SMAs; the second was the use of the framework by individuals, since team-based data gathering had not been implemented in the previous stage.

SMAs were not used for two main reasons. First, constructing proper SMAs requires a significant investment of man-hours by the hospital to supply proper data on the processes carried out in the chosen healthcare setting; this would have been difficult to arrange, due to the limited time of the staff involved. Second, due to the nature of the ward setting, both micro-level and macro-level processes may occur; hence various procedures are carried out by different staff throughout the entire ward environment. For this reason, it would not be feasible to include SMAs for a range of processes in the ward; they were therefore not utilised in this study.

Team-based brainstorming and safety walkabouts were not conducted in this study, although they were part of the initial plan. Despite significant effort was made to organize a team, it was difficult for participants to leave patients behind in the ward area for two straight hours, to join this research. Individual workshops were therefore arranged for each participant; each workshop took approximately two hours, including the RID Framework workshop and administration of the evaluation questionnaires.

The main procedure, drawn from the RID Framework, is shown below:

1. *System Familiarisation*: using the following inputs to increase understanding of how systems behave, interact with their environment, and pose risks to patients.
 - a. System Description: describing the system in textual and graphical format

- b. Sources of Risks: considering possible risk sources and asking what happens if these sources produce hazards
 - c. Nature of Hazards: considering the different nature of hazards
 - d. Time: considering time, working from past to future
2. *Identification of Risks*: identifying risks via brainstorming and safety walkabouts
 3. *Presentation of Risks*: presenting the list of risks in a clear manner, using a predefined risk log sheet

5. Results and Analysis

5.1. Results on the Application of the RID Framework

Each participant followed the framework individually, with facilitation and guidance provided by the author. The following inputs in the RID Framework were applied according to the procedure, to help provide a list of risks in the chosen ward setting.

5.1.1. System Familiarisation:

Step-I System Description: At this stage, the chosen ward setting was briefly described, textually and graphically. The textual description was accompanied by patient-centred maps participants were asked to draw, in order to enhance the understanding of the ward setting. By placing the patient at the centre, linked to a number of chains, a very simple figure was provided to the participants to help identify hazardous elements that might pose patient safety risks. After receiving the maps drawn by the participants, we were able to provide a more detailed visual map to increase understanding of a range of hazards that can affect patient safety in the chosen ward setting. This was helpful for participants in identifying a range of potential hazards.

Another useful input at this stage was the ward layout. Participants found the layout helpful in identifying physical hazard elements. Some high-level risks in particular (e.g., security at entrance doors, visibility of patient rooms, etc.) were initially captured by using the ward layout.

Step-II Sources of Risks: At this stage, the classification of risk sources was introduced to the participants. As highlighted earlier, this classification was based on the NPSA RCA

classification framework (NPSA, 2009) with some adjustments. Some participants stated that they had previously used this instrument in incident investigation, but had never used it as a checklist for proactive risk identification. A potential contribution was that previous knowledge of this classification increased the use of this input throughout the risk identification process. In addition to the knowledge gained from the visual system description, participants were now able to classify risk sources in the chosen ward area.

While only the main components of the classification were supplied to participants during the brainstorming session, the complete classification, with detailed components, was provided during the safety walkabout session. The full classification components were not presented during the brainstorming sessions because they could have inhibited the imagination of new risks. The presentation of the complete list of components was therefore delayed until the safety walkabout, when it enabled participants to use it as a checklist to help avoid missing potential sources of risks. It is expected that the inputs of the RID Framework will be used during both brainstorming and safety walkabout sessions. Moreover, participants were also encouraged to engage with other staff working in the ward area. As a good example of this, it was rewarding to see that one participant entered into a dialogue with a nurse regarding a fire procedure, taking into account the training, which identified this source of risk from the provided checklist. The participant asked the nurse about the fire procedure; the lack of knowledge about this was then identified by the participant as a potential risk arising from training issues relating to fire occurrences.

It was observed that participants found the classification of risk sources very helpful throughout the brainstorming session; it was also felt, however, that the full component lists in the NPSA RCA framework classification are too detailed to be used as a checklist in the short timeframe of a safety walkabout session. This was an expected outcome during the safety walkabout, because the classification was not specifically developed for use in a ward setting. One of the potential contributions of the RID Framework is expected to be the identification of a broad list of risks in a chosen area, and the use of this list as a specific checklist for use in future risk identification sessions.

Step-III Nature of Hazards: At this stage, the categorisation of hazards was introduced to the participants; none had used such a categorisation before. It was useful to stimulate the imagination of new risks in the ward environment; this, moreover, provided valuable insights into hazards of different natures that might occur in the complex and changeable ward

environment. For instance, throughout the safety walkabout, it was gratifying to observe that some participants were looking not only for obvious hazards, but also concealed hazards in different settings (*e.g.*, infection issues in the sluice room) within the ward environment.

Step-IV Time: Participants were asked at this stage to consider past, present, and possible future risks. The author selected eight specific incidents to share with participants, in order to raise awareness of past issues in the chosen ward area. The participants were expected to mention some examples of risks caused by different risk sources, and different in nature; moreover, it was pointed out that similar risks could occur in future. It was observed that review of previous incidents stimulated the imagination of new risks; this review also helped participants understand what went wrong in the chosen ward area, and, as with similar experiences in the past, what might go wrong in future due to change. One result was that some participants focused on possible changes expected in room settings and their future impact.

5.1.2. Identification of Risks:

Brainstorming and safety walkabouts, used as risk identification approaches, are included in the RID Framework. In the current study, difficulties were experienced in initiating risk identification during the brainstorming sessions, since most participants had little or no experience with this method. Participants experienced difficulties with knowing how to start identifying risks in these brainstorming sessions.

Similar issues were experienced during the safety walkabouts; however, the use of risk source classifications provided helpful guidance, in the form of a checklist for capturing patient safety risks. It was also observed participants began identifying risks in terms of their individual backgrounds: the consultant physician began by reviewing the drug charts and patient records, while the nurses started by identifying equipment-related risks, as they mostly interacted with this kind of thing in ward settings.

In the brainstorming sessions, the judgements of participants were more subjective, owing to the semi-structured brainstorming process (in contrast with a typical FMEA session, in which SMAs are strictly followed, and no further judgements are made regarding external risks). This made the motivation of participants an important factor affecting the success of the risk identification. Since the success of risk identification is partially related to the motivation of the participants, it can be noted that different results might have been obtained with a

different group of participants, or with the same participants at a different time. Moreover, more risks might have been captured with less (or no) time pressure.

5.1.3. Presentation of the Risks:

A risk log (as shown in Table 3) was provided to each participant, to record the risks they identified.

In the course of this case study, 120 risks were identified from the chosen ward setting. However, it was noted that some participants had to skip the identification of *causes* and *effects*, due to their limited time. Identifying the three components of risk — *hazard*, *cause*, and *effect* — was relatively new to the participants. A significant effort was needed to identify *causes* just after identifying *hazards*. Despite such issues experienced at the beginning of the study, the participants used the NPSA RCA classification framework to capture potential causes. It was rewarding to note that in some cases participants identified multiple causes and effects for a single hazard. Further, participants identified the lack of safety culture as a potential cause of risks. This was an expected contribution of the framework, which successfully raises awareness of safety culture.

5.2 Observation on Usability and Utility of the RID Framework

As described above, the questionnaire was designed to give participants the opportunity to provide feedback on the usability and usefulness of the RID Framework. The questions were selected to evaluate the usefulness of the framework, with respect to the identified requirements and components of the RID Framework.

The findings from the evaluation forms are presented in Table 5 and Table 6. Five-point scales (*poor: 1 – excellent: 5*) were used and numerical formats were employed to aid numerical analysis. Table 5 shows the average rate for each statement and how many of the seven participants agreed on each scale, according to their opinions of the usability of the framework.

--- Insert Table 5 about here ---

The questions above allowed participants to evaluate the usability of the main components of the framework, and their supporting role in risk identification. In general, the scores showed that the framework had a positive impact on risk identification. None of the questions resulted in strong disagreement, averaging neutral to disagreeing. It was also noted that there were considerably more responses falling into the 'agree' category than the 'strongly agree' category. As shown in the first question in Table 5, participants generally agreed that the framework was easy to use; similarly, participants mostly agreed that they would use the framework for risk identification in future. They also agreed that the use of sources of risk, nature of hazards, time, and system description were helpful, and increased the understanding of system while stimulating the imagination of new risks. Table 5 shows the quantitative data collected, but some qualitative data regarding the usability of the framework were also gathered, as follows:

"Defining hazard is most difficult part. Contributory factors framework is very good but too detailed." [GC-06]

"I found it confusing initially but do recognise that thinking about situations in a different way will help." [GC-07]

After the evaluation of the usability of the framework, the following section was used to gather feedback on the usefulness of the RID Framework. Table 6 shows the average rate for each statement, and how many of the seven participants agreed on each scale, according to their experience.

--- Insert Table 6 about here ---

As shown in Table 6, participants found the framework encouraging in its usefulness. All participants except one agreed that they were able to perform the RID Framework. As an expected benefit of the framework, participants generally agreed that they were now more aware of system-wide safety risks. While participants believed they would find the framework useful in their work, they also agreed that they would not have identified the same risks using another framework, or no framework.

Table 6 presents the quantitative data collected, but some qualitative data regarding the usefulness of the framework were also gathered, as follows:

“Framework made me think more broadly e.g. not just visual inspection but talking to staff, patients, looking [at] documentations, [reviewing] past incidents.” [GC-06]

“I believe it would be easier to apply to individual areas with some training. We do have many generic risk assessment[s] and most are appropriate. We don’t write many for each unit which would be more important and relative.” [GC-07]

5.3 Written Feedback in the Questionnaire

Six questions were asked in the last section of the questionnaire, to gain further feedback on the usefulness of the RID Framework. These questions sought to determine whether applying the framework had changed the participants’ attitudes regarding the identification of patient safety risks. The responses are summarised below:

- **Did the use of the Risk Identification Framework reveal any significant risks of which you were previously unaware? If so, could you describe them?** In keeping with the responses participants gave to the previous question (*see utility section, statement 8*), most stated that they are now aware of different risks, risks that could not have been identified without the use of the RID Framework. Because the framework revealed significant risks, participants found it helpful in stimulating the imagination of different types of risks in a structured way. Some comments are as follows:

“It helped me collect my thoughts and work through why risks occur.” [GC-03]

“Not hugely significant but concealed risks found in ward areas i.e. sluice room.” [GC-04]

- **Did you find the definition of a risk (hazard, potential cause, and potential effect) difficult to follow in risk identification? Did you find any of them more difficult to identify than others?** This question addressed an important aspect of presenting risks using the RID Framework. Most participants specifically mentioned the difficulties involved in identifying hazards as initial components of the risks. A few comments were also made regarding the complexity of the approach, particularly in identifying different components of each defined risk. A selection of answers to this question from several participants is presented below:

“It was difficult to follow at the time of the walkabout. Easier when looking back afterwards. Initially identified hazards as equipment that were then changed to organizational. Probably just the time factor in completing this today.” [GC-02]

“Yes, to begin with but this did become clearer the more I did.” [GC-04]

“Hazard: hard to define and categorise.” [GC-05]

“Hazard difficult to define.” [GC-06]

“I did initially get confused. Needed to ‘rethink’ the process for identifying risk.” [GC-07]

- **Have you ever thought about different sources of risk in risk identification before this project? Did you find it helpful to imagine relevant hazards and risks in this area?** Generally, participants found the identification of sources of risks helpful in imagining relevant hazards and risks. One participant also emphasised that visiting the area was more valuable when considering risk sources than trying to imagine what the risks were. Selected comments are presented below:

“Only briefly. Yes, it is helpful. Would be more helpful in my specific place of work.” [GC-01]

“Very helpful tool.” [GC-03]

“No, I find the standards on risk / incident forms very narrow — this encouraged broader thinking.” [GC-04]

“This is a wider view of hazards.” [GC-05]

“Yes, now more aware of some areas of hazards / risks than others. Found visiting the area more valuable than trying to imagine what the risks were.” [GC-06]

“Helpful, I would like to use this a bit more to really get the sense of improved identification of risk. I believe it will be good.” [GC-07]

- **Have you ever thought about the different nature of hazards in risk identification before this project? Did you find it helpful to imagine relevant hazards and risks in this area?** Categorisation of the different nature of hazards was found very helpful by the participants, in both the brainstorming and safety walkabout stages. The participants also pointed out the benefit of using such an input together with the ward layout. A selection of answers to this question is presented below:

“Very helpful tool.” [GC-03]

“No, I was not thinking of concealed or developing hazards and will use in service development.” [GC-04]

“Checking ward plan was useful. I haven’t done it before. It was a help.” [GC-05]

“Yes, again better to see area than try to imagine the risks.” [GC-06]

“Having the floor plan made it easy as could ‘visualize’ better. Perhaps looked at different things.” [GC-07]

- **Are there any notable omissions in the Risk Identification Framework? If so, could you describe them?** No negative comments were made on the content of the framework in general. However, participants did indicate three notable omissions from the framework, and while the first two (patient complaints and using a team-based approach) were already considered in the content of the framework; they were not included in this case study. The third comment was not taken into account in the development of the framework. During the case study, participants (mainly managers) several times highlighted the need to consider financial issues in safety studies. Their comments included the following:

“Not obvious. May think of something given time. Using a team approach may be beneficial.” [GC-04]

“Patient input?” [GC-05]

“Finance?” [GC-06]

- **Do you think this framework might be a good starting point for identifying possible risks in each department in the hospital?** Most participants made positive responses regarding the usability and usefulness of the framework. The comments about its practical benefits and possible benefits for cultural change were the main motivation for developing a new risk identification framework. The following is a selection of written answers to this question:

“It could be a useful tool which has some added detail and contributory factors over and above our risk assessment process.” [GC-02]

“Yes, this tool helps frame questions and discover cause of hazard. Will help managers and clinicians consider ‘ward culture’ which will help develop future models for managing risk and hazard [in] wards, clinics and hospitals.” [GC-03]

“Helpful addition — very detailed as a starting point to RMIS, complaints etc. This could be used to combine existing information to one single library.” [GC-05]

In summary, many comments were collected, including positive and negative views of the framework; the comments regarding the usefulness of the RID Framework, however, were mainly positive. Although significant efforts were made to limit bias and its impact on the validity of the outcomes, it could still be argued that the outcomes might have been different had the study been conducted in another healthcare setting and/or with more participants. Acknowledging such limitations, it can be said that applying and evaluating the RID Framework in other healthcare settings would strengthen the validity of the results. However, both qualitative and quantitative results derived at the evaluation stage can be claimed to serve as reliable indicators of what can be accomplished within the timeframe employed in the study.

6. Discussion

Throughout the case study, the RID Framework made available an integrated approach to proactive risk identification, employing a number of inputs from reactive and proactive tools. The framework helped identify as many relevant risks as possible. However, even after these efforts, two questions still remained, namely: whether (1) identified risks are realistic, and (2) all potential risks were identified through use of the framework.

The framework gave good results in terms of quantity of risks identified ($n = 120$). However, the quality of the results remains a question for the present, because no estimation can be made of what percentage of risks might actually result in harm.

Within the scope of risk management, a risk cannot be evaluated or mitigated until it is identified. Further, there might be no actions to take to avoid or diminish the effects of unidentified risks. Though this study had tended to lean towards identification, a clear strategy should be in place to balance effort between identification, assessment and mitigation. It may be true that a few well identified key risks would receive more attention from management, while too many risks with little analysis would get neglected; for this reason, it should be noted that the quantity of risks is not the only indicator of success, although quantity can breed quality (Smith et al., 2008). Hence the transition between the risk management stages should be well defined in order to develop an optimal risk mitigation strategy.

We observed in the course of this study that it is difficult to ensure that all possible risks are taken into account, and therefore the next stage of risk assessment should always be considered as an option. From this vantage, it appears that risk identification is a never-ending process, and the most difficult aspect of the risk assessment process is probably that it involves the highest level of uncertainty driving the scope of error of the evaluation. While all these factors indicate that a range of risks must be identified in the first place, it also encourages the use of a number of approaches for identifying different types of risks.

The contribution of the RID Framework can also be shown by referring to safety culture. The RID Framework aims first to contribute to organisations at the safety culture level, by encouraging workers to identify safety concerns proactively. The RID Framework, an integrated approach, is expected to cover all reactive results (*e.g.*, results of incident investigations) in its content. The framework also includes the safety walkabout process; hence, it is likely to cover a range of risks identified by pure safety walkabout studies (even more so, since checklists are also used in the RID Framework).

Based on the research activities carried out as described, the value of this novel framework lies in its ability to subsume the power of current methods in a systems approach, as well as considering future risks — this makes the approach prognostic, rather than merely reactive and proactive. The RID Framework suggests using future areas of change as prompts for imagining future risks. Therefore, the changes in technology, functions, and procedures within the seven healthcare categories are explicitly considered to potentially point to additional risks that may not emerge from the use of other traditional approaches. The results of this study still show, however, that the RID Framework should not be used as a stand-alone tool, and suggest the use of multiple approaches to provide a comprehensive list of risks.

Our findings should be considered in view of study limitations. For instance, while the framework suggests using less resource (*e.g.* cost and time) to encourage systems approaches in the identification of patient safety risks, in this study, we did not explicitly assess its resource intensiveness or benchmark with other tools and methods. This can be evaluated in future research to indicate what resources and support (*e.g.* minimum or ideal) needed for each stage of the RID Framework. Further, it should be noted that this study was conducted at a particular healthcare setting in one NHS trust with limited number of participants. It therefore remains unclear to what extent the finding of this study generalise the usability of

the framework to other type of healthcare settings, trusts, other countries, or even other types of industries. To obtain better results for validating the framework, further case studies can be conducted in different healthcare settings.

Finally, it should also be noted that simply identifying risks, without deep analysis, might have a negative impact on risk culture, as misidentification could generate bad decisions, resulting in real risks. This, in turn, recalls the idea that having a well-defined transition between identification and assessment helps to develop optimal risk mitigation strategies in healthcare organisations. If these are not considered in the risk identification process, designing or applying new tools (including the RID Framework) may result in a risk bureaucracy, but will not contribute to risk culture in healthcare.

7. Conclusions

The RID Framework aims to integrate the power of using both reactive and proactive approaches to help identify a list of patient safety risks by providing fundamental guidance to healthcare users. In this study, the RID Framework was developed and then applied through a case study. It was also evaluated to assess its usability and usefulness in risk identification in a real-world healthcare setting.

The application of the RID Framework was completed successfully. In general, it was noted that the framework can be of practical benefit to the risk identification process and potentially aid cultural change for safety improvement. Throughout the case study, 120 risks were identified.

The evaluation of the framework provided valuable insights into its usability and usefulness. Using mainly positive comments, participants agreed that the framework was useful in identifying risks proactively, with the help of the inputs embedded in the content of the framework. Participants also pointed out a few notable omissions that could be incorporated into the framework; these included, primarily, the need for input from patients, executing the framework as a team effort, and consideration of financial aspects.

The results indicated that the RID Framework can help improve the practice of risk identification in healthcare. It should be noted, however, that the results do not confirm that

the framework can identify all relevant risks in a given system. It is therefore suggested that the framework should not be used in isolation, but in conjunction with other tools and methods, in a structured way, so as to not undervalue risks identified using any other tools and methods. Otherwise, efforts along these lines would likely develop a risk bureaucracy, but not a risk culture.

Competing Interests

The authors declared no potential conflicts of interests with respect to the authorship and/or publication of this article.

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Tables

No	Characteristic			Requirement name	Potential benefit of the requirement to the current risk identification practice	Rationale behind the requirement					
	Input	Process	Output			Literature review	Content Analysis	Interview-based questionnaires	Comparison of the methods	SMAs Evaluation	FMEA Evaluation
1	✓	✓	✓	Systems-based approach	Increasing the understanding on how systems behave, interact with their environment and pose risks to patients	✓	✓	✓	✓	✓	✓
2	✓	✓	✓	Adaptability	Adaptable within a broader risk management context	✓		✓	✓		
3	✓	✓	✓	Considering current culture	Adaptable to the current safety culture to help strive for becoming more proactive	✓		✓			✓
4	✓	✓	✓	Less-resource intensiveness	Providing flexibility to add and remove inputs and methods depending on resources available	✓	✓	✓			✓
5	✓	✓	✓	Compatibility	Open to be used in line with other tools and methods	✓		✓	✓		✓
6	✓	✓	✓	Usability	Easy to be used by range of people from different backgrounds (e.g. consultants, nurses and managers)	✓		✓		✓	✓
7	✓	✓	✓	Practicality	Applicable in real healthcare settings	✓				✓	
8	✓	✓	✓	Flexibility	Open to be used by individuals or teams	✓					✓
9	✓			System description	Increasing system understanding to help identify system-related risks	✓		✓	✓		
10	✓			Categorisation on risk sources	Stimulating the imagination of new risks in complex healthcare systems	✓		✓	✓	✓	
No	Characteristic			Requirement name	Potential benefit of the requirement to the current risk identification practice	Rationale behind the requirement					
	Input	Process	Output			Literature review	Content Analysis	Interview-based questionnaires	Comparison of the methods	SMAs Evaluation	FMEA Evaluation
11	✓			Categorisation on nature of	Stimulating the imagination of new risks in changeable	✓		✓			✓

				hazards	healthcare systems						
12	✓			Considering from past to future	Along with the increased awareness on past experience, being proactive and prognostic to consider present and future changes	✓	✓				✓
13	✓			Using system mapping approaches	Identifying hot-spots by an SMA chosen through the rate of past incidents or interview with key system users	✓		✓		✓	✓
14		✓		Structured brainstorming	Considering different sources of risks in a structured way	✓					✓
15		✓		Safety walkabout with the use of checklist	Considering a detailed checklist during the safety walkabout to cover a range of risk sources	✓		✓			
16			✓	Utility of risk output	Increasing the understanding on risk theory to provide a list of risks in a clear manner	✓		✓	✓		
17			✓	Quality of risk output	Identifying realistic risks that can potentially impact on patient safety	✓					✓
18			✓	Quantity of risk output	Identifying as many relevant risks as possible to help provide a comprehensive list of risks	✓			✓		✓

Table 1 Capturing Requirements on Risk Identification²

SMA type	Organisational	Information	Task	Flow	Communication	System
Risk Sources						
Task-related risks			✓	✓		✓
Environmental risks				✓	✓	✓
Equipment-related risks		✓				✓
Communication risks		✓		✓	✓	✓
Organisational risks				✓	✓	✓
Staff-sourced risks	✓			✓		✓
Patient-sourced risks		✓				✓

² Further information on rationale behind requirements and reasoning behind the selection of each research method can be found in the Ph.D. dissertation submitted to the University of Cambridge, titled as “Design for Patient Safety: A Systems-based Risk Identification Framework” (Simsekler, 2015).

Table 2 SMAs and Characteristics of Risk Sources (Simsekler et al., 2018)

RISK IDENTIFICATION LOG

Name:	Job Title:	Ward / Clinic Area:	Date:
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REFERENCE LIST OF CONTIBUTORY FACTORS

This is the list of potential source/cause of risks associated with the task in the ward/clinic area stated above. Please consider all the references listed below.

Patient-related Risks	Staff-related Risks	Task-related Risks	Communication Risks	Equipment-related Risks	Environmental Risks	Organisational Risks
Clinical Condition	Physical Issues	Guidelines, Policies and Procedures	Verbal Communication	Displays	Administrative Factors	Organisational structure
Physical Factors	Psychological Issues	Decision Making Aids	Written Communication	Integrity	Design of Physical Environment	Priorities
Social factors	Social Domestic	Procedural or Task Design	Non verbal Communication	Positioning	Environment	Externally imported risks
Mental/ Psychological Factors	Personality Issues		Communication Management	Usability	Staffing	Safety culture
Interpersonal Relationships	Cognitive Factors				Work load and hours of work	Training and team-related risks

IDENTIFIED RISKS

No.	Source Type	Hazard (What can go wrong?)	Potential Cause (Why / How it could go wrong?)	Potential Effect (Who / What is at risk?)
1				

2				
3				
4				
5				

Table 3 Risk Identification Log

No.	Job title	Experience in the NHS	Training on Risk Management	Identifier
1	Consultant Physician	20 years	No	GC-01
2	Nurse	29 years	Yes, risk management	GC-02
3	Operations Manager	23 years	Yes, all	GC-03
4	Operations Manager	28 years	Yes, risk officer training	GC-04
5	Patient Safety Manager	11 years	Yes, RCA	GC-05
6	Divisional Lead Nurse	30 years	Yes, risk management	GC-06
7	Senior Clinical Nurse	20 years	Yes, risk officer training	GC-07

Table 4 Participants in RID Framework evaluation

Q.	Usability	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Ave.
1	I think the framework is easy to use	0	0	1	5	1	4.0
2	I think that I would like to use this framework when I perform risk identification	0	0	1	5	1	4.0
3	The framework goes into an appropriate level of detail to help me undertake risk identification	0	0	2	3	2	4.0
4	The components of the risk identification framework are well integrated	0	1	1	4	1	3.71
5	Most healthcare staff would learn to use this framework quickly	0	0	3	3	1	3.71
6	Considering system familiarization is helpful in the risk	0	2	1	2	2	3.57

	identification framework						
7	Considering different time (past to future) is helpful in risk identification	0	2	0	4	1	3.57
8	Considering different nature of hazards is helpful in risk identification	0	1	1	4	1	3.71
9	Considering different sources of risk is helpful in risk identification	0	2	0	1	4	4.0
10	The framework stimulates me to imagine new hazards and risks	0	0	1	3	3	4.29
11	The use of ward drawing is helpful in identifying possible hazardous points.	0	1	0	3	3	4.14
12	The use of contributory factors classification framework is helpful in risk identification.	0	0	3	2	2	3.86
13	Using past incident examples is helpful in imagining possible hazards and risks	1	0	1	1	4	4.0

Table 5 Participants' responses on the usability of the RID Framework

Q.	Utility	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Ave.
1	I could perform the RID Framework	0	1	0	5	1	3.86
2	I am more aware of system-wide safety risks	0	0	2	4	1	3.86
3	I found a change in my perception of safety hazards and risks	0	0	3	2	2	3.86
4	Using the framework would improve work practices	0	0	3	2	2	3.86
5	Using the framework would improve the understanding of risk identification in the NHS	0	2	0	3	2	3.71
6	Using the framework might help us have a specific risk library in each department	0	2	1	1	3	3.71
7	The RID Framework would be useful in my work	0	2	0	3	2	3.71
8	I think that I would have identified the same risks without using the RID Framework	1	3	3	0	0	2.26

Table 6 Participants' responses on the utility of the RID Framework

Figures

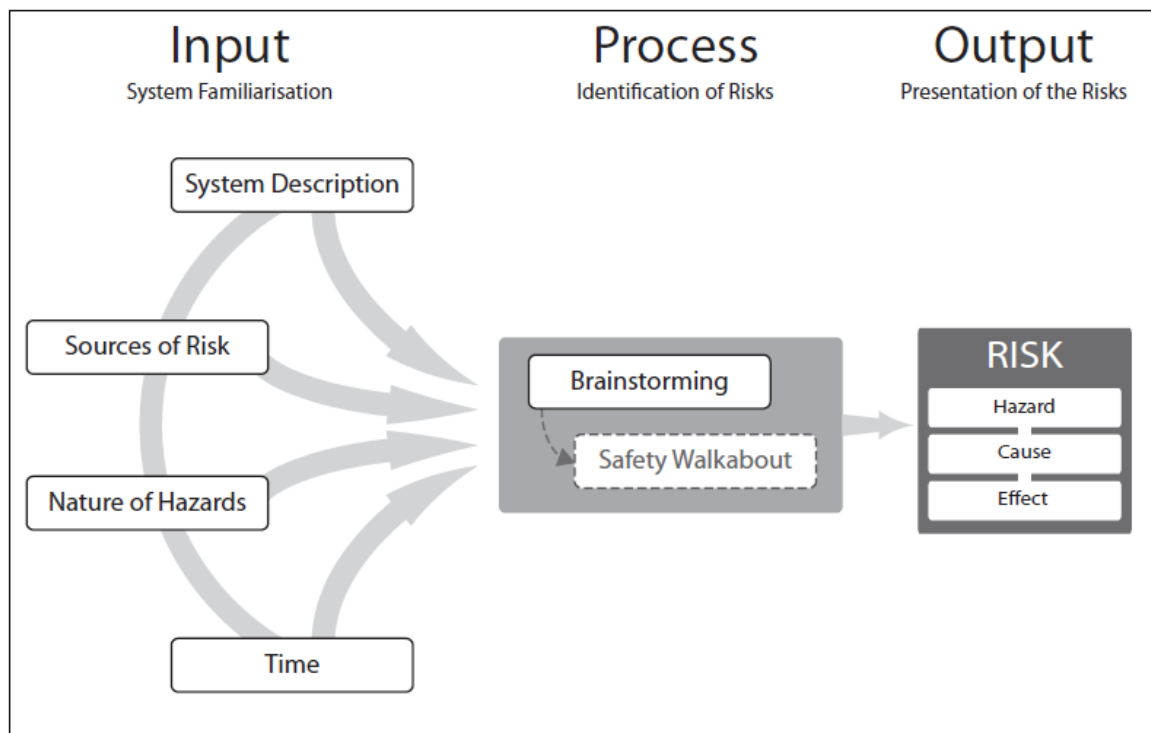


Figure 1 Risk Identification Framework in a simplistic manner

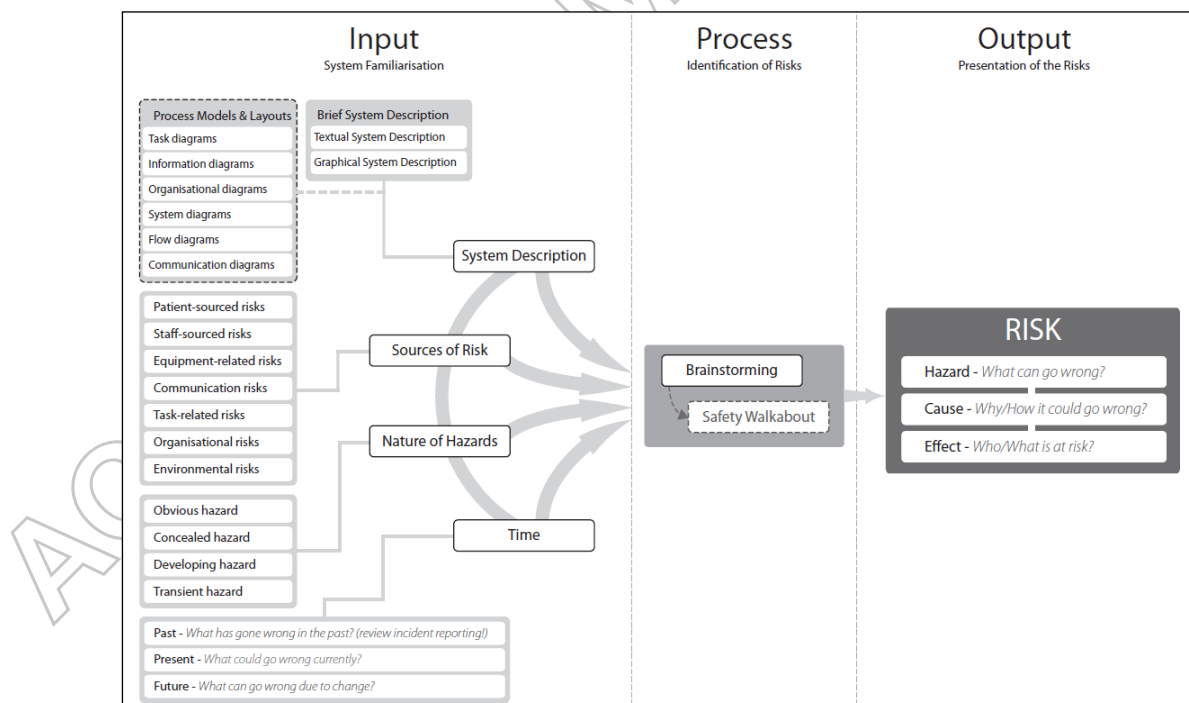


Figure 2 Risk Identification Framework